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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,387

01/14/2005

Reiner Luttmann

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/521,387	<b>Applicant(s)</b> LUTTMANN ET AL.	
	<b>Examiner</b> MICHAEL HOBBS	<b>Art Unit</b> 1797	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 01 July 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 1-19.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☒ Other: See Continuation Sheet.

/Michael A Marcheschi/  
Supervisory Patent Examiner, Art Unit 1797

Continuation of 3. NOTE: the claims have been amended to include the filtration step and supplying a signal to the harvest pump which was not previously presented and the limitation of a concentrated retentate was not previously presented with regards to the material removed from the bioreactor. It should be further noted that these amendments to the claims do not put the claims in a better form for appeal by either materially reducing or simplifying matters for appeal.

Continuation of 13. Other: in the second paragraph on page 9, applicant argues that the modification of Cornelissen would lead the skilled artisan away from Major since the skilled artisan would be discouraged from the combination. This is not found persuasive since there is no specific teaching within Cornelissen discouraging or teaching away from this reference and while the reference does a continuous filtration of the harvested product, Major also does this same process (see Fig. 1 of Major). Therefore, the references are analogous and drawn to similar processes. Furthermore, there is no suggestion that removing the whole cell culture as disclosed by Major would render the Cornelissen inoperative. Applicant further argues on the top of page 10 that the combination discourages or teaches away from the combination. The examiner disagrees with this characterization of the reference and the reason to combine was provided in the previous action.

In response to applicant's argument in the first full paragraph on page 10 that the skilled artisan would be discouraged from combining the references, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In the second paragraph on page 11, applicant argues that the applied reference of Cornelissen is not analogous art to the recitation of claim 1 since the reference does not disclose a balance connected to an analyzer in order to control an upstream feed pump. In response to applicant's argument that the Cornelissen reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the applied reference discloses the steps where an upstream feed pump is connected to a regulator and the reference is in the same field of endeavor as the instant application.

Starting on the last paragraph of page 11 and continuing to the second paragraph of page 12, applicant argues that the applied reference of Gruenberg does not disclose the first and second regulators, the analyzer, the control unit, the analytical system nor the cell concentration sensor. The applicant further argues that the relevant teachings have been extrapolated from the reference and that the balances are not connected to a second analyzer. The examiner disagrees with this characterization of the reference as all the upstream pumps and balances are connected to an analyzer or process computer (see Fig. 1 of Gruenberg).

Regarding applicant's arguments with the applied reference of Lucido starting on the bottom of page 12 and continuing to the bottom of page 13, applicant argues that reference does not a) render every recited element obvious in claim 1, b) that the turbidity sensor is not connected to a computer and does not test for cell concentration and c) the applied reference is non-analogous art.

In response to applicant's argument that Lucido does not disclose all the elements of claim 1, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Here, Lucido was used to correct the deficiency of the cell concentration sensor as a turbidity sensor can determine the concentration of cells within the bioreactor. Moreover, both Cornelissen and Gruenberg disclose sensors connected to a bioreactor and it would be a matter of simple substitution for the skilled artisan to use the turbidity sensor of Lucido in place of the sensors of Cornelissen and Gruenberg.

In response to applicant's argument that the Lucido reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Lucido discloses using a turbidity sensor to monitor the growth of cells within the interior of a bioreactor and is analogous in the sense that using a sensor, such as this, to monitor the growth of bacteria to process waste is the same as monitoring cell growth in a bioreactor. In both cases, this sensor is used to monitor and control a process and the skilled artisan would have found it obvious to monitor the process of Cornelissen, Major and Gruenberg with the sensor of Lucido barring any evidence to the contrary. With regards to applicant's statement that this rejection is based on conjecture, speculation and the assumption of undisclosed elements of multiple unrelated references as an improper grounds of rejection, this is merely attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.

In the second paragraph on page 14, applicant argues that the only way to achieve the claimed invention with the combination of Cornelissen, Major, Gruenberg, Lucido and Bartok is through impermissible hindsight. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regards to applicant's arguments regarding the rejection of claim 17 starting in the last paragraph on page 14 and continuing to the top of page 15, this argument is re-iterating the arguments applied to the rejection of claim 1 and have already been addressed.